IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re United States Patent Application of:		Docket No.:	4179-128
Applicants:	SHAH, Tilak M.	Conf. No.:	8353
Application No.:	10/815,282	Art Unit:	1711
Date Filed:	April 1, 2004	Examiner:	Thao T. Tran
Title:	EXTRUSION LAMINATE POLYMERIC FILM ARTICLE AND GASTRIC OCCLUSIVE DEVICE COMPRISING SAME	Customer No.:	23448

DECLARATION OF TILAK M. SHAH UNDER 37 CFR 1.132 IN U.S. PATENT APPLICATION NO. 10/815,282

1. My name is Tilak M. Shah. I have Bachelor of Science degrees in Chemistry and Physics from Bombay University, and Master's degree in Chemistry from the City College of New York. I have over twenty-five years of experience working with polyurethane, elastomers, and other polymers in various research, product development, and marketing roles for various corporations, including the Upjohn Company, Dow Chemical USA, Pacrim International, Inc., TS Polymers, Inc., Polygenex International, Inc., and Polyzen, Inc. I have been a member of the American Chemical Society and the Society of Plastics Engineers since 1972. In recent years, my expertise has been focused on the medical device industry. I have served as the President and CEO of Polyzen, Incorporated since 1997. Polyzen's primary business area include: (1) polymer formulation and compounding; and (2) development and assembly of medical devices, including medical balloons, stents, probes, organ bags, protective sleeves, and specialty tubing.

2. I have authored and co-authored a large number of technical papers and publications relating to polymers and elastomers, including: Thermoplastics Polyamide section in *Modern Plastics Encyclopedia*, 1985-1986; "Polyamide Elastomer" chapter in handbook of "Thermoplastics Elastomer", 1988; Radiopaque Polymer Formulation for Medical Devices, *Medical Device & Diagnostic Industry*, March 2000; Polyurethane Thin Film Welding for Medical Device Application, *Medical Device & Diagnostic Industry*, September 2002; Maximizing Tubing Functionality, Part I and Part II, *Medical Device & Diagnostic Industry*, October and November 2003; and Improved Process for Bonding Polymeric Thin Film to Textiles for Healthcare and other Applications, *Paper presented at Clemson University Medical Textile Conference*, March 2004.

3. I am named as an inventor or co-inventor on a large number of U.S. patents, foreign patents, and pending patent applications relating to polymers, polymeric articles, and methods for fabricating and using polymeric articles, including, for example, U.S. Patent Nos. 7,112,186; 6,805,662; 6,712,832; 6,663,646; 6,509,094; 6,492,012; 6,460,541; 6,352,077; 6,291,543; 6,258,869; 5,833,915; 5,799,333; 5,679,423; 5,644,798; 5,571,567; 5,554,673; 5,469,863; 5,245,195; 4,950,239; RE31,671; 4,202,957; 4,000,117; and 3,951,657. I am the inventor of the subject matter of the subject patent application.

4. By virtue of my education and work experience, I am highly familiar with methods for laminating and bonding polymer sheets, and with methods for forming medical balloons. Moreover, by virtue of my current employment, I maintain a high degree of familiarity the state-of-the-art advances and developments in the fabrication of medical balloons as they occur.

5. The amended claims of the instant U.S. Patent Application No. 10/815,282 are directed to a gastric occlusive device comprising a balloon that in an inflated state is non-pillowed and spheroidal in shape, formed from vacuum thermoformed half-sections of a multilayer film that are peripherally bonded together, with the film comprising a layer of sealing film and at least one layer of thermoplastic polymer film.

6. I understand that all of the claims of the instant patent application have been rejected. I have reviewed the substance of the Final Office Action dated February 22, 2007, along with U.S. Patent No. 6,976,950 to Connors et al. (hereinafter, "Connors") relied upon by the Examiner in the rejection of the claims. Based on my review of these documents, I have the following comments relating to Connors and the Final Office Action.

7. Connors mentions various methods of forming materials for inflatable attenuation devices (balloons), including "extrusion to prepare sheets, plugs, or tubular structures" (e.g., col. 16, line 63 – col. 17, line 7; col. 19, lines 27-29); "injection mold[ing] to fabricate intricately designed parts," (col. 19, lines 29-30); "compression mold[ing] to prepare films" (col. 19, lines 30-31); "dip-molded or extruded" (col. 22, lines 41-43); or "lamination, coextrusion, ... [or] spray molding" (col. 23, lines 62-67). Connors further refers to formation of balloons of a wide variety of shapes, including spherical, toroidal, spoked-wheel, horseshoe-like, mushroom-like, and banana-like forms. One skilled in the art would understand, however, that not every balloon fabrication method mentioned by Connors is compatible with every particular balloon shape that is mentioned by Connors.

8. In one embodiment described in connection with Figures 5 and 5A, Connors discloses formation of a balloon from a first component 74 and second component 76 bonded together by a seam 78, with the resulting balloon having a "generally circular profile" from above, but having a pillow-like appearance from the sides. *See* Connors Figures 5 and 5A; columns 11-12. A balloon of such pillow-like conformation is routinely obtained by peripherally sealing (e.g., welding) non-elastic thin polymeric sheets to one another, and then pressurizing the cavity formed therebetween.

9. The claims of the instant patent application require the use of multilayer film comprising at least one layer of thermoplastic film. Thermoplastics are generally understood to be non-elastic in character. As more fully discussed hereinafter, the only method of which I am aware to form a balloon that in an inflated state is non-pillowed and spheroidal in shape, from two peripherally bonded sections of a multilayer film comprising at least one thermoplastic polymeric film layer, is to first treat the sections of multilayer film by vacuum thermoforming. Absent the use of vacuum thermoforming, I am familiar with no other practical method for forming a balloon that in an inflated state is non-pillowed and spheroidal in shape, from two peripherally bonded sections of a multilayer film comprising at least one thermoplastic polymeric film layer.

10. In a balloon formed by peripherally bonding two conventional non-elastic sheets (with such sheets not being vacuum thermoformed), pillowing along the peripheral seam is a natural and inevitable result. Such pillowing is undesirable in balloons intended for gastric use. Pillowing creates involutions resulting in a profile, that in gastric use, tends to abrade the lining of the stomach. Moreover, pillowing tends to cause the seam of a gastric balloon to protrude outward, which in extreme cases can cause the seam to act as a cutting edge.

11. Several Exhibits are attached to demonstrate the distinctions between a balloon formed from peripherally bonded non-thermoformed sheets of a multilayer film including a thermoplastic film layer versus a balloon formed from peripherally bonded vacuum thermoformed sheets of the same multilayer film. Exhibits A1-A3 show deflated top, inflated top, and inflated side views, respectively, of a balloon , formed from peripherally bonded non-thermoformed sheets of a multilayer film including a thermoplastic film layer. As shown in Exhibit A1, from above the inflated view appears circular in profile – mimicking the appearance of the balloon illustrated in Figure 5 of Connors. Upon inflation of this first non-thermoformed balloon, involutions and an irregular shape appears along the seam (as visible in Exhibit A2), and a pillowed or flattened circular conformation is achieved (as visible in Exhibit A3). Exhibits B1-B3 show deflated top, inflated top, and inflated side views, respectively, of a different balloon, formed from vacuum thermoformed sheets of the same multilayer starting film used in the balloon of Exhibits A1-A3 and peripherally bonded to form a seam. Upon inflation of this second thermoformed balloon, the resulting seam is devoid of involutions and has a smooth and uniform shape (as visible in Exhibit B2), and a non-pillowed spheroid shape is achieved (as visible in Exhibit B3). The balloon pictured in Exhibits A1-A3 corresponds to the teachings of Connors, while the balloon pictured in Exhibits B1-B3 corresponds to the claims of the instant application.

12. Nothing in Connors teaches or remotely suggests the use of vacuum thermoforming, or any other method suitable for forming a balloon that in an inflated state is non-pillowed and spheroidal in shape, formed from sections of a multilayer film that are peripherally bonded together, with the film comprising a layer of sealing film and at least one layer of thermoplastic polymer film.. In other words, Connors contains no teachings that would enable one skilled in the art at the time the present invention was made to reproduce the subject matter of the amended claims.

13. One skilled in the art at the time the present invention was made would not have looked to vacuum thermoforming for fabricating balloons from multi-layer polymer sheets. Vacuum thermoforming has traditionally been used with thick films that are homogeneous in character, such as to create packaging trays and the like. The process of vacuum thermoforming tends to subject the working material to differential stresses as the material is deformed by heat and pressure to conform to the cavity of a vacuum thermoforming die. Such differential stresses have been generally considered to be detrimental in application to multi-layer polymer sheets –

particularly composite sheets formed from different material layers – due to the possibility of local or even bulk delamination of the individual layers under application of such stress. Considering the desired end use of a balloon capable of retaining pressurized fluid, the risk of delamination would have led one of ordinary skill in the art at the time the invention was made to adopt a method other than vacuum thermoforming for forming a spherical balloon, such as dip molding or the like.

14. In further support of the idea that the process of vacuum thermoforming was not well known in the art prior to my invention of the subject matter of the present application, I note that I am the recipient of U.S. Patent No. 6,712,832, which broadly claims methods for manufacturing low-pressure balloons from thin film polymeric materials, including the steps of heating the thermoplastic polymeric material thin film to a sufficient temperature for vacuum thermoforming thereof, forming first and second half-sections for a balloon from the thin film by vacuum suction, and bonding the first and second half-sections together along edges thereof. See, e.g., claim 1 of U.S. Patent No. 6,712,832 (which patent has already been made of record in the instant application). Such Patent was issued on March 30, 2004, and the underlying patent application was not published until April 17, 2003 (i.e., as U.S. Patent Application No. 2003/0074017 – which date is more than two weeks after the filing date of the instant U.S. Patent Application No. 10/815,282, and a month after the filing date of U.S. Patent Application No. 10/391,446 that matured into U.S. Patent No. 6,976,950 to Connors et al. In this regard, I understand that the disclosure of U.S. Patent No. 6,712,832 was not publicly available to third parties to support public awareness of its teachings.

15. Based on the failure of Connors to enable the subject matter of the amended claims of the instant patent application, and the lack of motivation in the art at the time the present invention was made to use vacuum thermoforming in the fabrication of balloons made from multi-layer sheets including at least one thermoplastic layer, there exists no basis for rejecting the amended claims of the instant patent application over Connors.

I declare under penalty of perjury that the facts set forth in this declaration are true and correct, that all statements made of my own knowledge are true, and that all statements made on information and belief are believed to be true. I have been hereby warned that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. § 1001, and that such willful false statements may jeopardize the validity of the application or any resulting registration.

Executed at APEX, North Carolina, this 20th day of April 2007.

Tilak M. Shah

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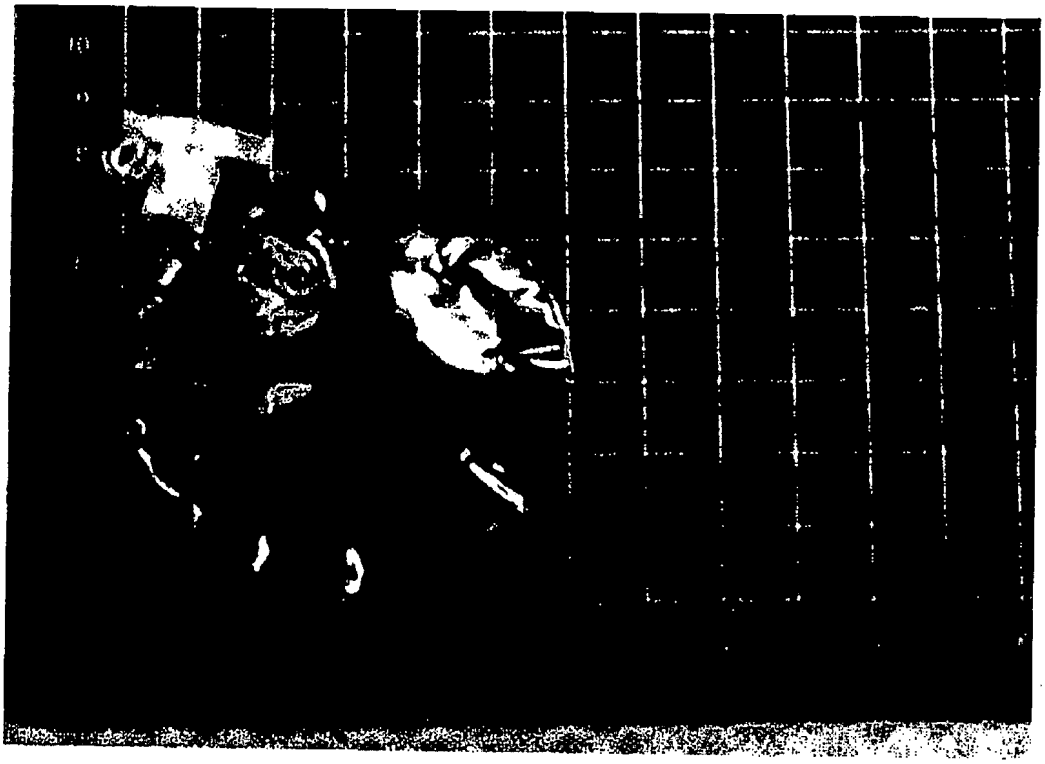
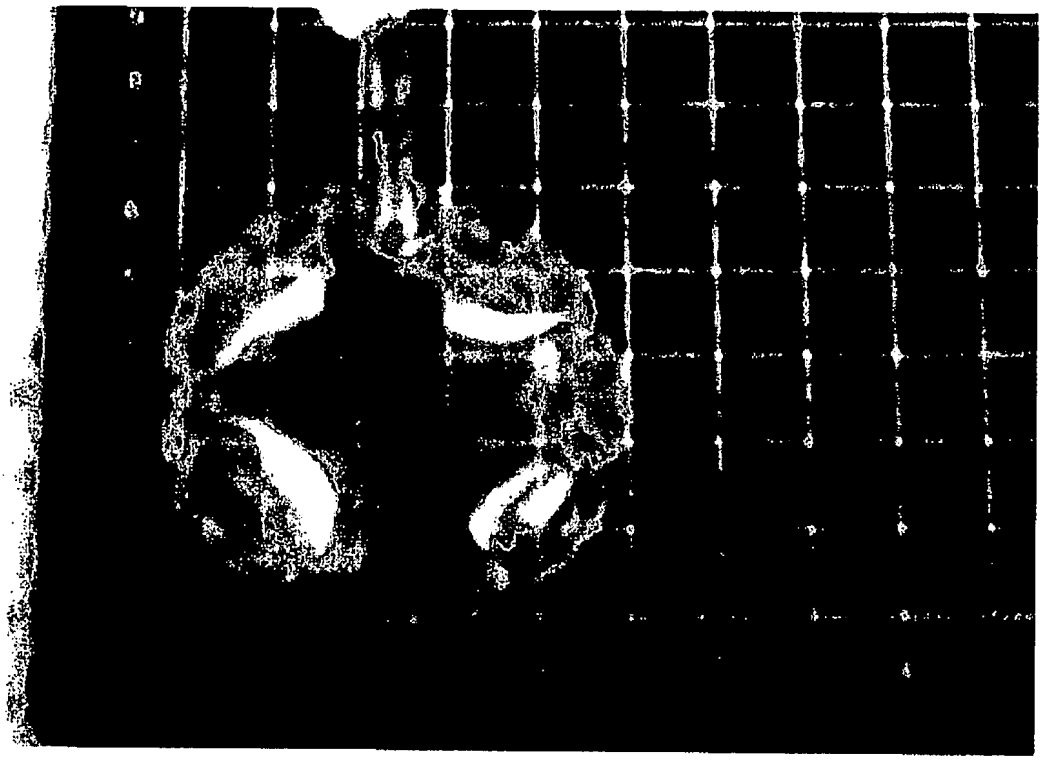
EXHIBIT A1



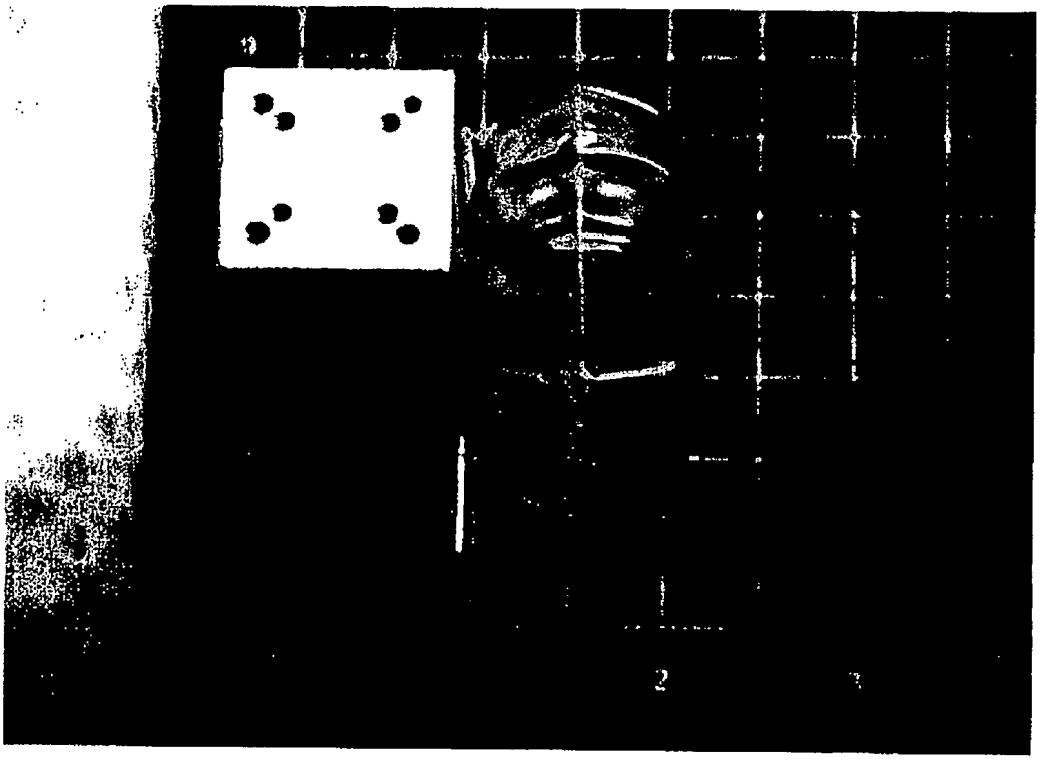
TOP VIEW OF UNINFLATED BALLON FORMED OF PERIPHERALLY BONDED *NON*-THERMOFORMED SHEETS

EXHIBIT A2



TOP VIEW OF INFLATED BALLON FORMED OF PERIPHERALLY BONDED *NON*-THERMOFORMED SHEETS

EXHIBIT A3

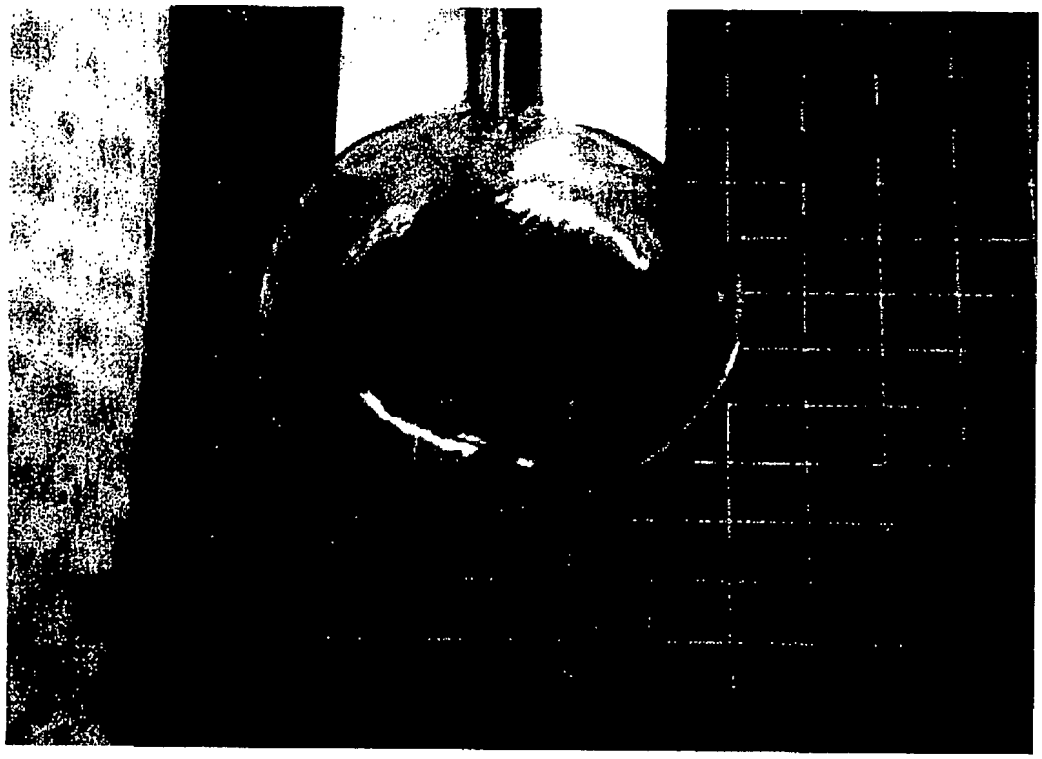


SIDE VIEW OF INFLATED BALLON FORMED OF PERIPHERALLY BONDED *NON*-THERMOFORMED SHEETS

EXHIBIT B1

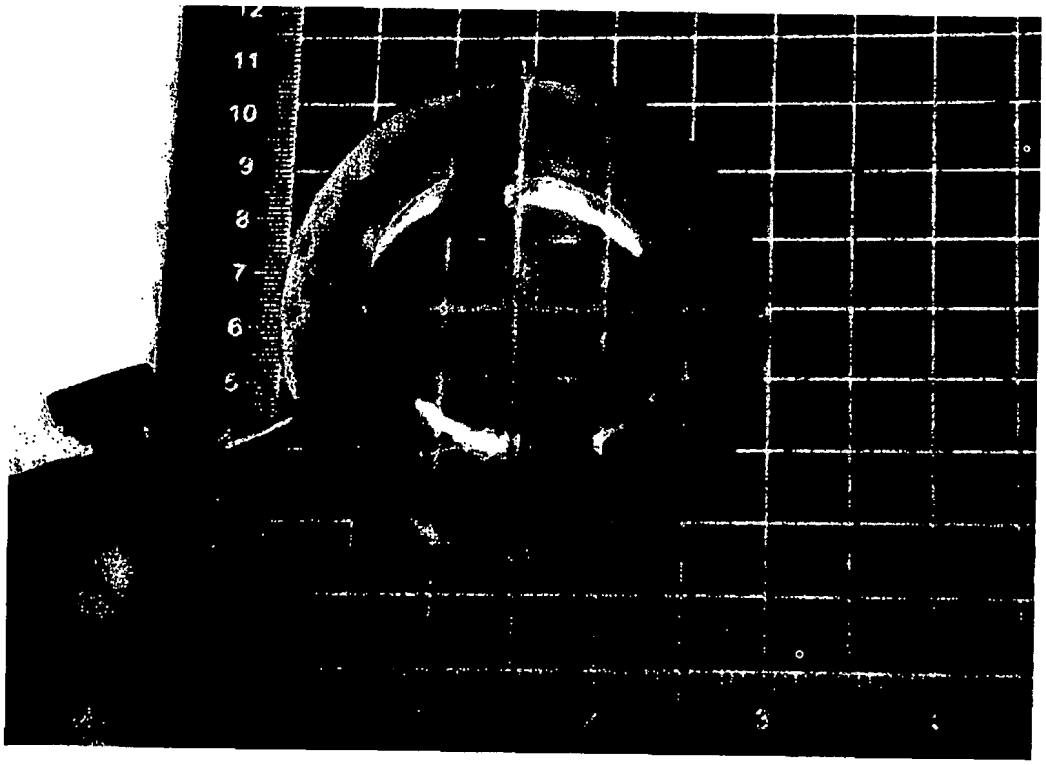
TOP VIEW OF UNINFLATED BALLON FORMED OF PERIPHERALLY BONDED VACUUM THERMOFORMED SHEETS

EXHIBIT B2



TOP VIEW OF INFLATED BALLON FORMED OF
PERIPHERALLY BONDED VACUUM-THERMOFORMED SHEETS

EXHIBIT B3



SIDE VIEW OF INFLATED BALLON FORMED OF PERIPHERALLY BONDED VACUUM-THERMOFORMED SHEETS